

SAFETY EVALUATION OF SINNA SIVAPPU MAATHIRAI - A SIDDHA HERBO-MINERAL DRUG

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ABSTRACT

Siddha Medical system has been practiced by Tamil speaking community in Northern and Eastern part of Sri Lanka and Southern part of India. *Sinna Sivappu Maathirai (SSM)* is a poly herbo-mineral drug prescribed for respiratory symptoms. Safety evaluation of *SSM* has not been carried out previously. Hence, this study was done to evaluate the safety evaluation of *SSM*. Ethical clearance was obtained from Ethical review committee, Faculty of Medicine, University of Jaffna and administrative approvals were obtained from indigenous medical authorities in Sri Lanka. Participants who were prescribed with *SSM* for the first time at Government Ayurvedic Hospital, Kaithady enrolled as Group I (12 to 18 years) and Group II (18 years and above). Sixty four participants in group I and 63 in group II were treated with *SSM* for one week with dose of 130 and 260 mg bd/pc with 2.5mL and 5mL of betel extract respectively. The evaluation was carried out at the day 0, end of 1st, 2nd, 4th, and 12th week of follow up visits. Among the study population, 51.97% (66) of participants were females. All the participants were single in group I and in group II, 68.25 % (43) were married. Among 127 participants, 50.39 % (64) was students and 24.41 % (31) was Skill Level II workers. Participants were presented with the symptoms of 100% (127) cough, 28.35% (36) breathing difficulties, 15.75% (20) chest pain when coughing and 06.30% (8) fever. The mean difference of AST, ALT, ALP, bilirubin and clinical data for indicating hepatotoxicity, blood urea, serum creatinine, uric acid, urine test and clinical data for indicating nephrotoxicity, Clinical data for indicating neurotoxicity, RBC, WBC, haemoglobin, platelets and WBC/DC for indicating hematotoxicity and blood mercury for indicating mercury intoxication between day 0 and follow up visits were not significantly (p -value ≥ 0.05) resulted. Hence it could be concluded that *SSM* is safe with the dose of 130 mg with 2.5 mL and 260 mg with 5 mL betel extract bd/pc for one week treatment for respiratory symptoms in the age range 12 to 18 years and 18 and above years in both sex respectively. The study should be followed as clinical trial with control group to evaluate the toxicity and validate the therapeutic effect of *SSM*.

Keywords: Siddha medicine, *SSM*, Herbo-mineral, Safety, Toxicity

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